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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,881

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Thomas R. Skwarek

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,881	Applicant(s) SKWAREK ET AL.	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-37, 41 and 43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-23, 28, 29 and 41-43 is/are allowed.
- 6) ☒ Claim(s) 33, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 34 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 6, paragraphs 3-5, filed 7 December 2007, with respect to the provisional non-statutory double patenting rejection of claims 1, 3, 5-11, 18, 24, 26, 30, 32, 38, 40 and 41 have been fully considered and are persuasive. For at least the reasons that the provisionally rejected claims have been cancelled, the double patenting rejection of claims 1, 3, 5-11, 18, 24, 26, 30, 32, 38, 40 and 41 has been withdrawn.

For clarification, claim 41 was correctly included in the double patenting rejection. Although the subject matter of claim 41 is similar to claims 19, 28 and 33, each of those claims provides for a method or a device invoking the 112, 6th paragraph "means for" language whereas claim 41 was presented as a standard structural device claim wherein the copending application need only be capable of the function recited in claim 41 to read on the claim. However, due to amendments to the copending application 10/441,784 during its natural course of prosecution, and due to the most recently filed amendment to claim 41 including the language "a processor configured to control" in line 6, the double patenting rejection has been obviated.

2. Applicant's arguments, see page 6, paragraph 6, filed 7 December 2007, with respect to the rejections to the claims made under 35 U.S.C. §102 (claims 3-32 and 38-40 as anticipated by Krakovsky et al.; claims 1, 4-11, 18, 30-32 and 38-40 as anticipated by Gerber et al.) have been fully considered and are persuasive. For at

least the reason that the rejected claims have been cancelled, the rejections under 35 U.S.C. §102 of claims 1, 3-32 and 38-40 have been withdrawn.

3. The rejection of claims 1, 4-11 and 18 under 35 U.S.C. §103(a) as unpatentable over Krakovsky'840 in view of Whitehurst'294 or Brenman'102 has been obviated due to the cancellation of said claims and is withdrawn.

4. The rejection of claims 1, 5-11, 18, 30-32 and 38-40 under 35 U.S.C. §102(e) or §103(a) as anticipated or obvious over Whitehurst'895 in view of Whitehurst'294 or Brenman'102 has been obviated due to the cancellation of said claims and is withdrawn.

5. Applicant's arguments, see page 7, paragraph 6 through page 9, paragraph 3; filed 7 December 2007, with respect to the rejection of claims 19-22 and 33-37 under §103(a) as unpatentable over Krakovsky'840 in view of Whitehurst'294 or Brenman'102 and further in view of Mann'171, as well as being obvious over Gerber'240 in view of Mann'171, have been fully considered and are persuasive. The §103(a) rejections of claims 19-22 and 33-37 have been withdrawn. Claims 4, 19-22, 24, 25, 27, 41 and 42 were similarly rejected under 35 U.S.C. §103(a) as being unpatentable over Whitehurst'895 in view of Mann'171. For at least the same reasons (see page 7, paragraph 6 through page 9, paragraph 3), the arguments are considered persuasive and the rejection of claims 4, 19-22, 24, 25, 27, 41 and 42 has been withdrawn.

6. Applicant's arguments, see page 10, paragraphs 1-3, filed 7 December 2007, with respect to the rejection of claims 28, 29, 41 and 41 under 35 U.S.C. §103(a) as unpatentable over Krakovsky'840 have been fully considered and are persuasive. The §103(a) rejection of claims 28, 29, 41 and 41 has been withdrawn.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber et al. (US 2004/0049240, hereinafter Gerber'240).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Regarding claim 33, Gerber'240 discloses a method of providing medical therapy to a patient (TITLE; ABSTRACT) comprising delivering a first pulse train to a prostate gland over a first period of time (abstract; paragraphs [44], [45], [47]); and delivering a second pulse train to the prostate gland over a second period of time, wherein the second pulse train is different than the first pulse train (ibid.; paragraph [49]; Table 2); and wherein the first and second pulse trains are delivered via one or more electrodes deployed on or implanted within cellular muscle tissue of the prostate gland (paragraphs [44], [45], [47]).

Regarding claims 35 and 36, Gerber'240 is considered to disclose a third and fourth pulse train to the prostate gland over a third and fourth periods of time (paragraph [49]) insomuch as Gerber'240 discloses delivery of multiple stimulation signals and illustrates a range of possible signals in Table 2.

Further regarding claims 33, 35 and 36, it is noted that a change in the fiber structure of the prostate gland is considered to be an inherent result of the application of the stimulation pulse frequencies over the given ranges of time. For example, electrical stimulation of a muscle causes it to contract, which is a change in the fiber structure of the muscle, even if only a temporary one. It is therefore understood that stimulation of the prostate gland would similarly result in a physiologically based change in the fiber structure, whether that change be of a temporary or permanent nature.

Still further regarding claims 33, 35 and 36, Gerber'240 discloses the invention substantially as claimed, but does not expressly disclose that the time periods of a first and second pulse train are on the order of one week. However, it would have been

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obvious to one of ordinary skill in the art at the time of the invention to use a training period on the order of a week, since it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art, where paragraph [47] of Gerber'240 establishes therapy parameters such as pulse width and therapy duration as result effective variables. Additionally or alternatively, it would have been obvious to try, to one skilled in the art, to continue stimulation for as long as necessary to achieve the desired result of changing the fiber structure of the prostate gland, wherein such a time period might be on the order of a week.

Allowable Subject Matter

9. Claims 19-22, 28, 29 and 41-43 are allowed.
10. The following is a statement of reasons for the indication of allowable subject matter:
11. Regarding independent claims 19 and 41, the Examiner is unable to find within the prior art, alone or in combination, a teaching of providing stimulation pulses directly to the muscle tissue of the prostate gland in a training sequence comprising a first pulse train and second pulse train delivered over the order of a week, wherein the second pulse train includes more pulses per unit time than the first pulse train, such that the fiber structure of the gland is physically changed.

12. Regarding independent claim 28, it is noted that Applicant is invoking §112, 6th paragraph through use of “means for” language. Examiner finds in the prior art similar deficiencies as those of claims 19 and 41 as described in paragraph 11 above.

13. Claims 34 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
27 March 2008

/George Manuel/
Primary Examiner